

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date Jan. 5, 2017			EPA Reg No./File Symbol 91813-	Page 1 of 23	
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406			Product UPL Fludioxonil Technical		
Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data</b>					
830.1550	Product Identity and Composition	50089601	UPL Delaware, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	50089601	UPL Delaware, Inc.	OWN	
830.1620	Description of Production Process	50089601	UPL Delaware, Inc.	OWN	
830.1650	Description of Formulation Process				Not required <sup>1</sup>
830.1670	Discussion of Formation of Impurities	50089601	UPL Delaware, Inc.	OWN	
830.1700	Preliminary Analysis	50089602	UPL Delaware, Inc.	OWN	
830.1750	Certified Limits	50089601	UPL Delaware, Inc.	OWN	
830.1800	Enforcement Analytical Method	50089601 50089602	UPL Delaware, Inc. UPL Delaware, Inc.	OWN OWN	
830.6302	Color	50089603	UPL Delaware, Inc.	OWN	
830.6303	Physical State	50089603	UPL Delaware, Inc.	OWN	
830.6304	Odor	50089603	UPL Delaware, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	50089604	UPL Delaware, Inc.	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	50089605	UPL Delaware, Inc.	OWN	
830.6315	Flammability	50089607	UPL Delaware, Inc.	OWN	Waiver <sup>2</sup>
830.6316	Explosibility	50089607	UPL Delaware, Inc.	OWN	Waiver <sup>3</sup>

Signature



Name and Title

Nicole O'Loughlin; Regulatory Consultant

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Applicant's/Registrant's Name & Address  
UPL Delaware, Inc.  
630 Freedom Business Center  
King of Prussia, PA 19406

Product  
UPI Fludioxonil Technical

Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	50089606	UPL Delaware, Inc.	OWN	
830.6319	Miscibility				Not required <sup>4</sup>
830.6320	Corrosion Characteristics	50089606	UPL Delaware, Inc.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required <sup>5</sup>
830.7000	pH	50089603	UPL Delaware, Inc.	OWN	
830.7050	UV/Visible Absorption	50089603	UPL Delaware, Inc.	OWN	
830.7100	Viscosity				Not required <sup>6</sup>
830.7200	Melting Point/Melting Range	50089603	UPL Delaware, Inc.	OWN	
830.7220	Boiling Point/Boiling Range				Not required <sup>7</sup>
830.7300	Density/Relative Density/Bulk Density	50089603	UPL Delaware, Inc.	OWN	
830.7370	Dissociation Constants in Water	50089607	UPL Delaware, Inc.	PL	
830.7520	Particle size, fiber length, diameter distribution	50089607	UPL Delaware, Inc.	OWN	Waiver <sup>8</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	50089607	UPL Delaware, Inc.	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	50089607	UPL Delaware, Inc.	PL	

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Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	50089607	UPL Delaware, Inc.	PL	
870.1100	Acute Oral Toxicity: Rat	50089608	UPL Delaware, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	50089609	UPL Delaware, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	50089610	UPL Delaware, Inc.	OWN	
870.2400	Primary Eye Irritation: Rabbit	50089611	UPL Delaware, Inc.	OWN	
870.2500	Primary Dermal Irritation	50089612	UPL Delaware, Inc.	OWN	
870.2600	Dermal Sensitization	50089613	UPL Delaware, Inc.	OWN	
<b>Generic Data</b>					
850.2100	Acute Avian Oral Toxicity	43124102		OLD GAP	See endnote <sup>9</sup>
850.2200	Acute Avian Dietary Toxicity	43124103 43124104		OLD OLD	See endnote <sup>10</sup>
850.2400	Wild Mammal Toxicity				Not required <sup>11</sup>
850.2300	Avian Reproductive Toxicity	43080007 43080006		OLD OLD	See endnote <sup>12</sup>
850.2500	Simulated or Actual Field Testing				Not required <sup>13</sup>

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Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	Freshwater Fish Toxicity	43080008 43080009		OLD OLD	See endnote/ Waiver <sup>14</sup>
850.1010	Freshwater Invertebrate Toxicity	43080010		OLD	See endnote <sup>15</sup>
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	43080013 43080011 43080012		OLD OLD OLD	See endnote <sup>16</sup>
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	49407901	Syngenta Crop Protection	PAY	See endnote <sup>17</sup>
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required <sup>18</sup>
850.1400	Fish Early Life Stage (Freshwater)	43080014 44382302		OLD OLD	See endnote <sup>19</sup>
850.1400	Fish Early Life Stage (Saltwater)				Not required <sup>20</sup>
850.1500	Life Cycle Fish				Not required <sup>21</sup>
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	44382320		OLD	See endnote <sup>22</sup>
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required <sup>23</sup>
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required <sup>24</sup>
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required <sup>25</sup>
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Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
SS-WholeSed	Whole Sediment: Chronic Invertebrates (Freshwater and Marine)				Not required <sup>26</sup>
850.3020	Honey Bee Acute Contact Toxicity	43080047		OLD	See endnote <sup>27</sup>
850.3030	Honeybee Toxicity of Residues on Foliage				Not required <sup>28</sup>
850.3040	Field Testing for Pollinators				Not required <sup>29</sup>
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required
870.6200	Acute Neurotoxicity – Rat				Waive <sup>30</sup>
870.3100	90-Day Oral: Rodent	43080026		OLD	See endnote <sup>31</sup>
870.3150	90-Day Oral: Non-Rodent	43080029		OLD	See endnote <sup>32</sup>
870.3200	21/28-Day Dermal Toxicity	43080030		OLD	See endnote <sup>33</sup>
870.3250	90-Day Dermal Toxicity				Not required
870.3465	90-Day Inhalation Toxicity	49522706	Syngenta Crop Protection	PAY	Waive <sup>34</sup>
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity	49522707	Syngenta Crop Protection	PAY	See endnote <sup>35</sup>
870.4100	Chronic Oral Rodent	43080037		OLD	See endnote <sup>36</sup>
870.4200	Carcinogenicity	43080032 43080033 43080037		OLD OLD OLD	See endnote <sup>37</sup>

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Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3700	Reproduction/Developmental Toxicity Screening Test	43080034 43080035		OLD OLD	See endnote <sup>38</sup>
870.3800	2-Generation Reproduction: Rat	43080036		OLD	See endnote <sup>39</sup>
870.6300	Developmental Neurotoxicity Study				Not required <sup>40</sup>
870.5100	Bacterial Reverse Mutation Test	43080038		OLD	See endnote <sup>41</sup>
870.5300, 830.5375	In vitro Mammalian Cell Assay	43152501 43080040		OLD OLD	See endnote <sup>42</sup>
870.5385, 870.5395, 870.5450, 870.5550	In vivo Cytogenetics and Other Effects	43080042 43080041 43080043 43080039 43080044		OLD OLD OLD OLD OLD	See endnote <sup>43</sup>
870.7485	Metabolism and Pharmacokinetics	43080045 43080046 43445901 43445902		OLD OLD OLD OLD	See endnote <sup>44</sup>
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration				Not required <sup>45</sup>
870.7800	Immunotoxicity	48478502	Syngenta Crop Protection	PAY	See endnote <sup>46</sup>

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Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1100	Dermal Exposure – Outdoor		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>47</sup>
875.1200	Dermal Exposure – Indoor				Not required
875.1300	Inhalation Exposure – Outdoor		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>47</sup>
875.1400	Inhalation Exposure - Indoor				Not required
875.1500	Biological Monitoring		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>47</sup>
875.1600	Data Reporting and Calculations		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>47</sup>
875.1700	Product Use Information		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>47</sup>
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues				Not required <sup>48</sup>
875.2200	Soil Residue Dissipation		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>
875.2300	Indoor Surface Residue Dissipation				Not required

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Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2400	Dermal Exposure		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>
875.2500	Inhalation Exposure		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>
875.2600	Biological Monitoring		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>
875.2700	Product Use Information				Not required
875.2800	Descriptions of Human Activity		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>
875.2900	Data Reporting and Calculations		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>
875.3000	Nondietary Ingestion Exposure		Agricultural Re-Entry TF Outdoor Residential Exposure TF	OWN OWN	See endnote <sup>49</sup>

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King of Prussia, PA 19406

Product

UPI Fludioxonil Technical

Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet Size Spectrum				Not required <sup>50</sup>
202-1	Droplet Size Spectrum				Not required <sup>50</sup>
850.4100	Tier 1: Seedling Emergence	48526503	Syngenta Crop Protection	PAY	See endnote <sup>51</sup>
850.4150	Tier 1: Vegetative Vigor	48526504	Syngenta Crop Protection	PAY	See endnote <sup>52</sup>
850.4400, 850.4500	Tier 1: Aquatic Plant Growth				Not required <sup>53</sup>
850.4100	Tier 2: Seedling Emergence	48526503	Syngenta Crop Protection	PAY	See endnote <sup>51</sup>
850.4150	Tier 2: Vegetative Vigor	48526504	Syngenta Crop Protection	PAY	See endnote <sup>52</sup>
850.4400, 850.4500	Tier 2: Aquatic Plant Growth				Not required <sup>53</sup>
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required
835.1110	Activated Sludge Sorption Isotherm				Not required <sup>54</sup>
835.2120	Hydrolysis	43152502		OLD	See endnote <sup>55</sup>
835.2240	Photodegradation in Water	43496302 44382308		OLD OLD	See endnote <sup>56</sup>
835.2410	Photodegradation in Soil	43496303 44382308		OLD OLD	See endnote <sup>57</sup>

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2370	Photodegradation in Air				Not required
835.3110, 835.3220, 835.3280	Ready biodegradability; Porous Pot Study; Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater				Not required <sup>58</sup>
835.4100	Aerobic Soil Metabolism	43380513 46294501 47169301 47169302 47169312 47169313 47169314 48996602 48996603 48996604	Syngenta Crop Protection IR-4 IR-4 IR-4 IR-4 IR-4 Syngenta Crop Protection Syngenta Crop Protection Syngenta Crop Protection	OLD PAY PL PL PL PL PL PAY PAY PAY	See endnote <sup>59</sup>
835.4200	Anaerobic Soil Metabolism	47169303	IR-4	PL	See endnote <sup>60</sup>
835.4300	Aerobic Aquatic Metabolism	47169304	IR-4	PL	See endnote <sup>61</sup>
835.4400	Anaerobic Aquatic Metabolism				Not required <sup>62</sup>

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835.1230	Leaching/Adsorption/Desorption	44382311 44382312 44382313 44382309 44382310		OLD OLD OLD OLD OLD	See endnote <sup>63</sup>
835.1410	Volatility – Laboratory				Not required <sup>64</sup>
835.8100	Volatility – Field				Not required <sup>64</sup>
835.6100	Soil Field Dissipation Study	44703505 44703538		OLD OLD	
835.6200	Aquatic Sediment Field Dissipation Study				Not required <sup>64</sup>
835.6300	Forest Field Dissipation Study				Not required <sup>64</sup>
835.6400	Combination and Tank Mixes				Not required
835.7100	Ground Water Monitoring				Not required <sup>64,65</sup>
850.6100	Environmental Chemistry Methods				Not required <sup>64</sup>

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860.1300	Nature of the Residue: Plants	43080050		OLD	
		43143301		OLD	
		43960410		OLD	
		44554201		OLD	
		44554202		OLD	
		44554203		OLD	
		44703537		OLD	
		44926101		OLD	
860.1300	Nature of the Residue: Livestock	43470601		OLD	
		43470602		OLD	
		44382323		OLD	
860.1850	Confined Rotational Crops	43960409		OLD	
		44198401		OLD	

Signature 	Name and Title Nicole O'Loughlin; Regulatory Consultant	Date Jan. 5, 2017
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**DATA MATRIX**

Date Jan. 5, 2017		EPA Reg No./File Symbol 91813-		Page 13 of 23	
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406			Product  UPI Fludioxonil Technical		
Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Residue Analytical Methods	43080051		OLD	
		43080052		OLD	
		43080054		OLD	
		43080055		OLD	
		43960411		OLD	
		43960412		OLD	
		43960413		OLD	
		43960414		OLD	
		44554204		OLD	
860.1360	Multiresidue Method	43080053		OLD	
860.1380	Storage Stability	43690403		OLD	
		44382332		OLD	
		44554205		OLD	

Signature



Name and Title

Nicole O'Loughlin; Regulatory Consultant

Date

Jan. 5, 2017

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## DATA MATRIX

Date Jan. 5, 2017			EPA Reg No./File Symbol 91813-		Page 14 of 23
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406			Product UPI Fludioxonil Technical		
Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: root and tuber vegetables	43960417	IR-4	OLD	
		43960418		OLD	
		44554210		OLD	
		45682301		PL	
		47169310		PL	
		47161104		PL	
		47161108		PL	
860.1500	Magnitude of the Residue in Plants: bulb vegetables	44615602 46196501	IR-4	OLD PL	
860.1500	Magnitude of the Residue in Plants: leafy vegetables	44554207	IR-4	OLD	See endnote <sup>66</sup>
		45945001		PL	
		46006701		PL	
		48437305		PL	
		48437403		PL	
		48481701		PL	
		48499801		PL	

Signature 	Name and Title Nicole O'Loughlin; Regulatory Consultant	Date Jan. 5, 2017
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## DATA MATRIX

Date Jan. 5, 2017

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Applicant's/Registrant's Name &amp; Address

UPL Delaware, Inc.  
630 Freedom Business Center  
King of Prussia, PA 19406

Product

UPI Fludioxonil Technical

Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Brassica vegetables	44703529		OLD	
		45726001	IR-4	PL	
		45726002	IR-4	PL	
		45726101	IR-4	PL	
		45726102	IR-4	PL	
		45839801	IR-4	PL	
		47169311	IR-4	PL	
860.1500	Magnitude of the Residue in Plants: legume vegetables	44554208		OLD	
		46014701	IR-4	PL	
		46014702	IR-4	PL	
		46014703	IR-4	PL	
		46016701	IR-4	PL	
		46016702	IR-4	PL	
		46016703	IR-4	PL	
860.1500	Magnitude of the Residue in Plants: fruiting vegetables	47161101	IR-4	PL	
		48437304	IR-4	PL	
		48437401	IR-4	PL	
		48437402	IR-4	PL	

Signature



Name and Title

Nicole O'Loughlin; Regulatory Consultant

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## DATA MATRIX

Date Jan. 5, 2017	EPA Reg No./File Symbol 91813-	Page 16 of 23
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406	Product UPI Fludioxonil Technical	

Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: cucurbit vegetables	44554209 47161106	IR-4	OLD PL	
860.1500	Magnitude of the Residue in Plants: cereal grains	43124110 43690404 43960416 44715105 43124111 43690404 44554206 44715108		OLD OLD OLD OLD OLD OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: nongrass animal feeds				See endnote <sup>67</sup>
860.1500	Magnitude of the Residue in Plants: herbs and spices	45795301 45795401 47161103	IR-4 IR-4 IR-4	PL PL PL	
860.1500	Magnitude of the Residue in Plants: canola/rape	44703528 44703530		OLD OLD	See endnote <sup>68</sup>
860.1500	Magnitude of the Residue in Plants: cotton	44490802		OLD	
860.1500	Magnitude of the Residue in Plants: peanut				See endnote <sup>69</sup>

Signature 	Name and Title Nicole O'Loughlin; Regulatory Consultant	Date Jan. 5, 2017
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## DATA MATRIX

Date Jan. 5, 2017	EPA Reg No./File Symbol 91813	Page 17 of 23
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406	Product UPL Fludioxonil Technical	

Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
86C.1500	Magnitude of the Residue in Plants: cramte				See endnote <sup>70</sup>
860.1500	Magnitude of the Residue in Plants: flax				See endnote <sup>71</sup>
860.1500	Magnitude of the Residue in Plants: jojoba				See endnote <sup>72</sup>
860.1500	Magnitude of the Residue in Plants: lesquerella				See endnote <sup>73</sup>
860.1500	Magnitude of the Residue in Plants: safflower				See endnote <sup>74</sup>
860.1500	Magnitude of the Residue in Plants: sunflower				See endnote <sup>75</sup>
860.1520	Magnitude of the Residue in Processed Food (or Feed: root and tuber vegetables	43960417 43960418		OLD OLD	
860.1520	Magnitude of the Residue in Processed Food (or Feed: legume vegetables	46014701 46014702 46014703 46016701 46016702 46016703	IR-4 IR-4 IR-4 IR-4 IR-4 IR-4	PL PL PL PL PL PL	
860.1520	Magnitude of the Residue in Processed Food (or Feed: fruiting vegetables	47161101	IR-4	PL	

Signature 	Name and Title Nicole O'Loughlin; Regulatory Consultant	Date Jan. 5, 2017
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**DATA MATRIX**

Date Jan. 5, 2017	EPA Reg No./File Symbol 91813-	Page 18 of 23
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406	Product  UPI Fludioxonil Technical	

Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Magnitude of the Residue in Processed Food or Feed: cereal grains	43124110 43690404 43960416 44715105 43124111 43690404 44554206 44715108		OLD OLD OLD OLD OLD OLD OLD OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: canola/rape	44703528 44703530		OLD OLD	See endnote <sup>76</sup>
860.1520	Magnitude of the Residue in Processed Food or Feed: cotton	44490802		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: peanuts				See endnote <sup>77</sup>
860.1520	Magnitude of the Residue in Processed Food or Feed: flax				See endnote <sup>78</sup>
860.1520	Magnitude of the Residue in Processed Food or Feed: safflower				See endnote <sup>79</sup>
860.1520	Magnitude of the Residue in Processed Food or Feed: sunflower				See endnote <sup>80</sup>

Signature 	Name and Title Nicole O'Loughlin; Regulatory Consultant	Date Jan. 5, 2017
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## DATA MATRIX

Date Jan. 5, 2017			EPA Reg No./File Symbol 94813-		Page 19 of 23
Applicant's/Registrant's Name & Address UPL Delaware, Inc. 630 Freedom Business Center King of Prussia, PA 19406			Product UPI Fludioxonil Technical		
Ingredient Fludioxonil (Chemical Code 71503, CAS Number 131341-86-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	43960413 43960415		OLD OLD	
860.1400	Nature and Magnitude of the Residue in Potable Water				Not required
860.1400	Magnitude of the Residue in Fish				Not required
860.1400	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required
860.1460	Magnitude of the Residue in Food Handling Establishments				Not required
860.1900	Field Rotational Crops				Not required <sup>81</sup>

Signature



Name and Title

Nicole O'Loughlin; Regulatory Consultant

Date

Jan. 5, 2017

## Endnotes for UPL Delaware, Inc. UPI Fludioxonil Technical Data Matrix

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- <sup>1</sup> **830.1650** - These data are not required for the registration of a technical grade active ingredient. See 830.1620 for production process information.
- <sup>2</sup> **830.6315** - UPL Delaware, Inc. requests a waiver from the requirement of this data requirement since UPI Fludioxonil Technical is a solid and does not contain flammable components. Please refer to the Confidential Statement of Formula for UPI Fludioxonil Technical.
- <sup>3</sup> **830.6316** - UPL Delaware, Inc. requests a waiver from this data requirement because fludioxonil does not have the chemical bonds or functional groups associated with explosive chemicals.
- <sup>4</sup> **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. UPI Fludioxonil Technical is a solid technical material and therefore this data requirement is not applicable.
- <sup>5</sup> **830.6321** - This guideline is not required for registration of a technical grade material.
- <sup>6</sup> **830.7100** - These data are required when the product is a liquid. UPI Fludioxonil Technical is a solid and these data are not required.
- <sup>7</sup> **830.7220** - This guideline is not required because UPI Fludioxonil Technical is not a liquid at room temperature. Please refer to 830.7200 for melting point data.
- <sup>8</sup> **830.7520** - UPL Delaware, Inc. is seeking a waiver for this data requirement for UPI Fludioxonil Technical because the product is not a fibrous material nor is not water insoluble.
- <sup>9</sup> **850.2100** - MRID 43124102 is acceptable and satisfies the data requirement as per the June 17, 2011 Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments in Support of the Registration Review of Fludioxonil (DP Barcodes 384856 and 387808) (Problem Formulation) and Nov. 8, 2011 Response to the Initial 60-Day Public Comments on "Registration Review - Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments in Support of the Registration Review of Fludioxonil (6/17/2011; DP Barcodes 384856, 387808) (DP Barcode 39421) (EFED Response to Comments). The Problem Formulation and EFED Response to Comments also required the submission of passerine data; it appears these data have not yet been submitted.
- <sup>10</sup> **850.2200** - The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>11</sup> **850.2400** - The Problem Formulation states that these data are not required.
- <sup>12</sup> **850.2300** - The studies cited are supplemental or acceptable, but satisfy the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>13</sup> **850.2500** - The Problem Formulation states that these data are not required.
- <sup>14</sup> **850.1075** - MRID Numbers 43080008 and 43080009 are classified as acceptable and satisfy the data requirement as per the Problem Formulation and EFED Response to Comments. The Problem Formulation also required data on the species used for the fish life cycle study. However, since UPL is proposing to register fludioxonil only as a seed treatment, these data are not required. In addition, UPL is not proposing to register any formulations containing chlorothalonil and propiconazole; therefore, end-use data are not cited.
- <sup>15</sup> **850.1010** - MRID 43080010 was classified as acceptable and satisfies the data requirement as per the Problem Formulation and EFED Response to Comments. UPL is not proposing to register any formulations containing chlorothalonil, propiconazole, or cyprodinil; therefore, end-use data are not cited. In addition, since UPL is proposing to register fludioxonil only as a seed treatment, additional data citations are not required.
- <sup>16</sup> **850.1025, 850.1035, 850.1045, 850.1055, 850.1075** - These data are only conditionally required for seed treatment uses. However, conservatively, UPL is citing the MRID Numbers 43080011-13 (data on the technical product) which were classified as acceptable and satisfy the data requirement as per the Problem Formulation. Typical end-use product data are not cited.
- <sup>17</sup> **850.1300** - Although these data are only conditionally required for seed treatment uses, UPL is citing data that were recently submitted in response to the data gap identified in the Problem Formulation.



## Endnotes for UPL Delaware, Inc. UPI Fludioxonil Technical Data Matrix

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- <sup>18</sup> **850.1350** – These data are not required for seed treatment uses because the limited use patterns do not meet the criteria for requiring these data.
- <sup>19</sup> **850.1400** – These data are only conditionally required for seed treatment uses. However, conservatively, UPL is citing the MRID Numbers 43080014 and 44382302 which were classified as supplemental but satisfy the data requirement as per the Problem Formulation
- <sup>20</sup> **850.1400** – These data are not required for seed treatment uses because the limited use patterns do not meet the criteria for requiring these data.
- <sup>21</sup> **850.1500** – These data are not required for seed treatment uses because the limited use patterns do not meet the criteria for requiring these data.
- <sup>22</sup> **850.1710, 850.1730, 850.1850** – Although not specifically required for seed treatment uses, UPL has conservatively cited MRID 44382320. This study is supplemental, but satisfies the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>23</sup> **850.1950** – The Problem Formulation states that these data are not required.
- <sup>24</sup> **850.1735** – The Problem Formulation states that these data are not required.
- <sup>25</sup> **850.1740** – The Problem Formulation states that these data are not required.
- <sup>26</sup> **SS-WholeSed** – The Problem Formulation states that these data are required. However, these data would not be required for seed treatment uses (the Problem Formulation states that these organisms may be exposed to fludioxonil in water via run-off and spray drift, which are not applicable for the limited use patterns proposed by UPL).
- <sup>27</sup> **850.3020** – Although not specifically required for seed treatment uses, UPL has conservatively cited MRID 443080047. The study cited is acceptable and satisfies the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>28</sup> **850.3030** – The Problem Formulation states that these data are not required.
- <sup>29</sup> **850.3040** – The Problem Formulation states that these data are not required.
- <sup>30</sup> **870.6200** – The June 13, 2011 Fludioxonil; Human Health Assessment Scoping Document in Support of Registration Review (DP Barcodes D384857 and D387809) (Scoping Document) identified this data requirement as a data gap; it appears a waiver request was submitted to satisfy this data requirement. The July 22, 2015 Fludioxonil Section 3 Registration for Use on Carrots, Stone Fruit, Group 12-12, and Rapeseed, Subgroup 20A; Human Health Risk Assessment (DP Barcode D426863) (2015 Human Health RA) states that HASPOC determined that neurotoxicity data were not required for fludioxonil.
- <sup>31</sup> **870.3100** – The study cited was classified as acceptable and satisfies the data requirement as per the 2015 Human Health RA. Note: only one rodent species is required to be cited; therefore, mouse data are not cited.
- <sup>32</sup> **870.3150** – The study cited was classified as acceptable and satisfies the data requirement as per the 2015 Human Health RA.
- <sup>33</sup> **870.3200** – The study cited was classified as acceptable and satisfies the data requirement as per the 2015 Human Health RA.
- <sup>34</sup> **870.3465** – The Scoping Document identified this data requirement as a data gap; it appears a waiver request was submitted to satisfy this data requirement.
- <sup>35</sup> **870.6200** – The Scoping Document identified this data requirement as a data gap; it appears these data were submitted to satisfy this data requirement.
- <sup>36</sup> **870.4100** – The study cited was classified as acceptable and satisfies the data requirement as per the 2015 Human Health RA.
- <sup>37</sup> **870.4200** – The studies cited were classified as acceptable and satisfy the data requirement as per the 2015 Human Health RA.
- <sup>38</sup> **870.3700** – The studies cited were classified as acceptable and satisfy the data requirement as per the 2015 Human Health RA.

## Endnotes for UPL Delaware, Inc. UPI Fludioxonil Technical Data Matrix

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- <sup>39</sup> **870.3800** – The study cited was classified as acceptable and satisfies the data requirement as per the 2015 Human Health RA.
- <sup>40</sup> **870.6300** – The 2015 Human Health RA states that these data are not required for fludioxonil.
- <sup>41</sup> **870.5100** – The study cited was classified as acceptable and satisfies the data requirement as per the 2015 Human Health RA.
- <sup>42</sup> **870.5300, 830.5375** – The studies cited were classified as acceptable and satisfy the data requirement as per the 2015 Human Health RA.
- <sup>43</sup> **870.5385, 870.5395, 870.5450, 870.5550** – The studies cited were classified as acceptable and satisfy the data requirement as per the 2015 Human Health RA.
- <sup>44</sup> **870.7485** – The studies cited in the 2015 Human Health RA do not appear to correspond to fludioxonil. Therefore, previously submitted metabolism data on fludioxonil data are cited and are believed to satisfy the data requirement.
- <sup>45</sup> **870.7600** – The 2015 Human Health RA states that these data are not required for fludioxonil.
- <sup>46</sup> **870.7800** – The Scoping Document identified this data requirement as a data gap; it appears these data were submitted to satisfy that data requirement.
- <sup>47</sup> **875.1100, 875.1300, 875.1500, 875.1600, 875.1700** – UPL Delaware, Inc. is a member of the Agricultural Handlers Exposure Task Force (AHETF). A letter of authorization for reliance on AHETF data can be provided upon request.
- <sup>48</sup> **875.2100** – These data are not required for seed treatment uses.
- <sup>49</sup> **875.2200, 875.2400, 875.2500, 875.2600, 875.2800, 875.2900, 875.3000** – UPL Delaware, Inc. is a member of Agricultural Re-Entry Task Force (ARTF) and Outdoor Residential Exposure Task Force (ORETF). A letter of authorization for reliance on ARTF and ORETF data can be provided upon request.
- <sup>50</sup> **201-1, 202-1** – These data are not required for seed treatment uses.
- <sup>51</sup> **850.4100** – The Problem Formulation and EFED Response to Comments identified this data requirement as a data gap; it appears these data have been submitted under 48526503. UPL is not proposing to register fludioxonil in combination with other active ingredients and is limited to seed treatment uses only.
- <sup>52</sup> **850.4150** – The Problem Formulation and EFED Response to Comments identified this data requirement as a data gap; it appears these data have been submitted under 48526504. UPL is not proposing to register fludioxonil in combination with other active ingredients and is limited to seed treatment uses only.
- <sup>53</sup> **850.4400, 850.4500** – These data are not required for seed treatment uses.
- <sup>54</sup> **835.1110** – The Problem Formulation and EFED Response to Comments identified this data requirement as a data gap. However, these data are not relevant for seed treatment uses.
- <sup>55</sup> **850.2120** – The study cited is acceptable and satisfies the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>56</sup> **850.2240** – The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>57</sup> **850.2410** – The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation and EFED Response to Comments.
- <sup>58</sup> **835.3110, 835.3220, 835.3280** – The Problem Formulation and EFED Response to Comments identified this data requirement as a data gap. However, these data are not relevant for seed treatment uses.
- <sup>59</sup> **835.4100** – Although the studies cited are supplemental, they satisfy the data requirement as per the Problem Formulation and EFED Response to Comments based on additional information submitted by Syngenta (MRID 48996602), but that data on metabolites were required to be submitted. It appears those data were submitted under MRID Numbers 48996603 and 48996604.
- <sup>60</sup> **835.4200** – The study cited is acceptable and satisfies the data requirement as per the Problem Formulation and EFED Response to Comments. Supplemental data that did not satisfy the data requirement are not cited.

## Endnotes for UPL Delaware, Inc. UPI Fludioxonil Technical Data Matrix

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- <sup>81</sup> **835.4300** – Although the study cited is classified as supplemental, it satisfies the data requirement as per the Problem Formulation and EFED Response to Comments and no additional data are required.
- <sup>62</sup> **835.4400** – The EFED Response to Comments states that these data are not required.
- <sup>63</sup> **835.1230** – The studies cited are acceptable or supplemental and satisfy the data requirement as per the EFED Response to Comments.
- <sup>64</sup> **835.1410, 835.8100, 835.6200, 835.6300, 835.7100, 850.6100** – These data are not required based on the limited proposed use patterns of only seed treatment uses.
- <sup>65</sup> **835.7100** – The Problem Formulation states that these data are not required.
- <sup>66</sup> **860.1500** – Foliar residue data were not cited.
- <sup>67</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in nongrass animal feeds.
- <sup>68</sup> **860.1500** – Foliar residue data were not cited.
- <sup>69</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in peanuts.
- <sup>70</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in crambe. Also, see rapeseed/canola residue citations.
- <sup>71</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in flax.
- <sup>72</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in jojoba.
- <sup>73</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in lesquerella.
- <sup>74</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in safflower.
- <sup>75</sup> **860.1500** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in sunflower.
- <sup>76</sup> **860.1520** – Foliar residue data were not cited.
- <sup>77</sup> **860.1520** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in peanuts.
- <sup>78</sup> **860.1520** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in flax.
- <sup>79</sup> **860.1520** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in safflower.
- <sup>80</sup> **860.1520** – No data have been submitted to support this use pattern because it appears that termination of residue data show that there are no residues in sunflower.
- <sup>81</sup> **860.1900** – These data are not required based on the limited proposed use patterns of only seed treatment uses.